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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,965	11/28/2000	Nils Lonberg	014643-009031US	9526
7278	7590	12/20/2004	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			WEHBE, ANNE MARIE SABRINA	
			ART UNIT	PAPER NUMBER

1632

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,965

Applicant(s)

LONBERG ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57,59-61,64,66-68,71 and 78-82 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57,59-61,64,66-68,71 and 78-82 is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. ____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Applicant's after-final amendment and response received on 11/5/04 have been entered. Claims 76-77 have been canceled and new claims 81-82 have been added. Claims 57, 59-61, 64, 66-68, 71, and 78-82 are currently pending in the instant application.

Those sections of Title 35, US code, not included in this action can be found in a previous office action.

Double Patenting

The rejection of claims 57, 64, and 71 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-3 of U.S. Patent No. 5,625,126 (4/29/97), hereafter referred to as the '126 patent, is withdrawn in view of applicant's amendments to the claims. The '126 patent does not teach a transgenic mouse comprising in its genome the five specific human light chain Vk segments recited in the claims as amended.

The rejection of claims 57, 64, and 71 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 5,789,650 (8/4/98), hereafter referred to as the '650 patent is withdrawn in view of applicant's amendments to the claims. The '650 patent does not teach a transgenic mouse comprising in its genome the five specific human light chain Vk segments recited in the claims as amended.

The rejection of claims 57, 64, and 71 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No.

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5,877,397 (3/2/99), hereafter referred to as the '397 patent, is withdrawn in view of applicant's amendments to the claims. The '397 patent does not teach a transgenic mouse comprising in its genome the five specific human light chain Vk segments recited in the claims as amended.

Claim Rejections - 35 USC § 102

The rejection of claims 57, 59-61, 64, 66-68, and 71 under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,150,584 (11/21/00), hereafter referred to as Kucherlapati et al., is withdrawn in view of applicant's amendments to the claims. Kucherlapati et al. does not teach a transgenic mouse comprising in its genome the five specific human light chain Vk segments recited in the claims as amended.

Claims 57, 59-61, 64, 66-68, 71, and 78-82 are free of the prior art and allowable at this time.

This application is in condition for allowance except for the following formal matters:

The disclosure is objected to because of the following informalities: the specification as filed is missing pages 135-140. See the transmittal of new application filed on 11/28/00, which states that 284 pages of specification were filed, rather than 291.

As this application is a direct continuation of parent application 08/758,417, which contained the missing pages, and as the instant specification contains on page 291 the statement that the contents of patent applications cited in the specification are incorporated by reference in

their entirety, it is suggested that applicants provide the missing pages by way of amendment, including the statement that no new matter is being incorporated and that the missing pages have been incorporated by reference.

In view of the amount of material to added to the instant specification, a substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a).

A substitute specification must not contain new matter. The substitute specification must be submitted **with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text.** The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

Furthermore, it is noted that applicant's have previously filed amendments to the specification, in particular the amendment of 12/13/01, which included more than 44 pages of amendments to the specification. As a result of these amendments, the interlineations or cancellations made in the original specification could lead to confusion and mistake during the issue and printing processes, particularly in view of the requested substitute specification. **Accordingly, it is requested that the substitute specification be prepared relative to the originally filed specification and amended to include the previous amendments to the**

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specification, particularly those filed on 12/13/01, as well as the newly requested amendment to include pages 135-140 discussed above. See 37 CFR 1.125 and MPEP § 608.01(q).

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 9:30-6:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, **the new technology center fax number is (571) 273-8300**. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE, PH.D.
PRIMARY EXAMINER

